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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,730	12/15/2003	Jo Klaveness	NIDN-10314	1951

7590 10/11/2006

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,730	KLAVENESS ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 - 29, drawn to a targetable diagnostic and / or therapeutic agent comprising gas-containing or gas-generating material, classified in class 424, subclass 9.52.

II Claims 31 – 36, drawn to a method of generating enhanced images of a human or non-human animal body, classified in class 600, subclass 437.

III. Claims 37 and 38, drawn to a method for *in vitro* investigation of targeting by an agent, classified in class 435, subclass 4.

NOTE: In addition to the elected Group above, applicant is requested to elect a single species related to the composition of the gas. For example, a *specific* gas from the distinct group thereof as set forth in the claims (e.g. claims 2 – 4) to which the elected Group will be limited should be selected. The different compounds included therein are a very diverse set and are independent and distinct structures, including air, hydrogen, selenium hexafluoride, perfluorinated ether, perfluoropropane, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, applicant is requested to elect a single species related to the composition of the gas. For example, a *specific* stabilizing agent from the distinct group thereof as set forth in the claims (e.g. claims 5 or 8) to which the elected Group will be limited should be selected. The different compounds included therein are a very diverse set and are independent and distinct structures, including filmogenic protein, polymer material,

surfactant, phosphatidylserine, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, applicant is requested to elect a single species related to the composition of the gas. For example, a *specific* vector from the distinct group thereof as set forth in the claims (e.g. claim 12) to which the elected Group will be limited should be selected. The different compounds included therein are a very diverse set and are independent and distinct structures, including antibodies, growth factors and peptide hormones, oligonucleotides, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, applicant is requested to elect a single species related to the composition of the therapeutic agent. For example, a *specific* therapeutic compound from the distinct group thereof as set forth in the claims (e.g. claim 21) to which the elected Group will be limited should be selected. The different compounds included therein are a very diverse set and are independent and distinct structures, including antifungal agents, vitamins, enzymes, sedatives, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using the product. For example, the gas-containing agent of Group I can be used for

therapeutic purposes in addition to *diagnostic* purposes. Furthermore, the process for using the product as claimed can be practiced with another materially different product because the process of generating enhanced images can be practiced with materially different compounds, such as barium sulfate for x-ray imaging or gadolinium chelate complexes for MRI imaging.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using the product. For example, the gas-containing diagnostic and/or therapeutic agent of Group I can also be used for *in vivo* imaging, which has a different mode of operation than the method of Group III, which is practiced *in vitro*.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different methods have different modes of operation because the imaging method in Group II is used *in vivo*, while the targeting method of Group III is practiced *in vitro*.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the

inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

It is requested that applicant also reply to this requirement by including (i) an election of species for search purposes. NOTE: This single disclosed species will name a single *specific* gas, a single *specific* stabilizing agent, a single *specific* vector, and a single *specific* therapeutic agent. An exemplified species should be elected to show clear support in the specification for the elected species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER